



NORTH CAROLINA JOURNAL OF INTERNATIONAL LAW AND COMMERCIAL REGULATION

Volume 31 | Number 4

Article 5

Summer 2006

How Necessity May Preclude State Responsibility for Compulsory Licensing under the TRIPS Agreement

James Thuo Gathii

Follow this and additional works at: <http://scholarship.law.unc.edu/ncilj>

Recommended Citation

James T. Gathii, *How Necessity May Preclude State Responsibility for Compulsory Licensing under the TRIPS Agreement*, 31 N.C. J. INT'L L. & COM. REG. 943 (2005).

Available at: <http://scholarship.law.unc.edu/ncilj/vol31/iss4/5>

This Article is brought to you for free and open access by Carolina Law Scholarship Repository. It has been accepted for inclusion in North Carolina Journal of International Law and Commercial Regulation by an authorized editor of Carolina Law Scholarship Repository. For more information, please contact law_repository@unc.edu.

How Necessity May Preclude State Responsibility for Compulsory Licensing under the TRIPS Agreement

Cover Page Footnote

International Law; Commercial Law; Law

How Necessity May Preclude State Responsibility for Compulsory Licensing Under the TRIPS Agreement

James Thuo Gathii[†]

I. Introduction	943
II. Necessity as a Basis for Precluding Wrongfulness Under Customary International Law	945
A. Summary of the Preconditions for Relying on a Plea of Necessity: Essential Interest	951
B. Grave and Imminent Peril	953
C. Contribution and Jus Cogens	954
D. The Obligations of the TRIPS Agreement.....	954
E. Applying the Plea of Necessity to the HIV/AIDS Pandemic in Sub-Saharan Africa: Essential Interest..	956
III. Conclusions	967

I. Introduction

The need to facilitate and improve access to affordable and essential medicines for those with fatal or life threatening diseases like HIV/AIDS, malaria, and tuberculosis is often framed in humanitarian terms or as permissible exceptions to the protection of patents under the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement. In this article, I argue that an approach based on rules of State responsibility under international law might provide an equally persuasive basis for improving access to affordable and essential medicines. Strengthening legal justifications such as those pursued here has intrinsic value insofar as it enhances and complements the growing range of justifications for improving affordable access to essential medicines for indigent peoples. My thesis is that countries with major health pandemics, such as HIV/AIDS, may

[†] George E. Pataki Professor of International Commercial Law, Albany Law School. Thanks to Elaine Haonian Lu, Kristen Northrup, Stephen Gruberg, Michael Kenneally and Claude Shelverton for their research assistance.

engage in targeted compulsory licensing of essential medicines to facilitate access to affordable medicines for their citizens without bearing State responsibility for departing from the patent protections of the TRIPS Agreement. More specifically, I argue that the defense of necessity may preclude a finding of liability against countries that depart from the provisions of the TRIPS Agreement when they engage in targeted compulsory licensing that was part of a larger program addressing other facets of the HIV/AIDS pandemic.

Necessity is a customary international legal principle that precludes State responsibility for violations of international legal obligations under certain conditions. To plead necessity as a ground for precluding wrongfulness of an international obligation, a State must show that the internationally wrongful act was the only way for the State to safeguard against a grave and imminent peril.¹ The HIV/AIDS pandemic in many sub-Saharan African countries rises to this level of gravity and imminent peril. A State must also show that the internationally wrongful act does not seriously impair an essential interest of the State or States towards which the obligation exists.² I argue that the latter is a more problematic precondition to demonstrate in order to justify invoking necessity as a defense to engaging in targeted compulsory licensing. However, I argue for balancing the competing interests in favor of the long term health needs of sub-Saharan African countries experiencing the adverse consequences of the pandemic relative to the patent rights of pharmaceutical companies. In other words, my argument is neither that pharmaceutical patent rights are not important, nor that the long term health challenges associated with the HIV/AIDS pandemic necessarily prevail over patent rights; rather, I argue that advancing necessity as a ground for precluding responsibility proceeds from the premise that there is now a widely recognized need to balance the rights of patent holders with the rights of consumers patented products. The Doha Declaration on TRIPS and Public Health of 2001 and the proposed Article 31 *bis* of the

¹ *Report of the International Law Commission on the Work of its Thirty-Second Session*, art 33(1), U.N. Doc. A/35/10 (1980), reprinted in [1980] 2 Y.B. Int'l L. Comm'n pt. 2 at 1, 26-34, U.N. Doc. A/CN.4/SER.A/1980/Add.1 (Part 2) [hereinafter *Thirty-Second Session Report*].

² See *id.*

TRIPS Agreement definitively embrace the view that the TRIPS Agreement ought to be read and applied as balancing the rights of producers and users of patented pharmaceutical products.

II. Necessity as a Basis for Precluding Wrongfulness Under Customary International Law

The necessity defense for precluding wrongfulness is a rule of customary international law.³ As such, this defense arguably falls within the jurisprudence of the World Trade Organization (WTO), since the WTO judiciary interprets WTO treaties in light of “any relevant rules of international law applicable in relations between parties.”⁴ Indeed, the TRIPS Agreement cannot be construed to exclude the possibility of invoking the defense of necessity as long as countries with an HIV/AIDS pandemic are doing everything in their power to address the crisis, in addition to engaging in targeted reverse engineering and parallel importing as part of a comprehensive HIV/AIDS policy framework.

Article 25 of the 2001 Draft Articles on the Responsibility of States for Internationally Wrongful Acts provides the circumstances under which necessity can be invoked to preclude the *wrongfulness* of a violation of an international legal obligation.⁵ Under this Article:

³ Case Concerning the Gabčíkovo-Nagymaros Project (Hung v. Slov), 1997 I.C.J. LEXIS 2, 70-71 (Sept. 27, 1997).

⁴ Vienna Convention on the Law of Treaties art. 31(3)(c), May 23, 1969, 1155 U.N.T.S. 331, 8 I.L.M. 679. Article 31(3)(c) of the Vienna Convention of the Law of Treaties is now incorporated in Article 3.2 of the World Trade Organization’s (WTO) Dispute Settlement Understanding which provides in part that the clarification of “the existing provisions of those [WTO] agreements [should be] in accordance with customary rules of interpretation of public international law.” Article 3.2 of the Understanding on Rules and Procedures Governing the Settlement of Disputes, Dec. 15, 1993, General Agreement on Tariffs and Trade-Multilateral Trade Negotiations—Results of the Uruguay Round, 33 I.L.M. 112, 115 (1994). Notably, in *United States-Shrimp*, the Appellate Body in dicta noted that WTO treaties ought to be read “in light of contemporary concerns of the community of nations.” Appellate Body Report, *United States—Import Prohibition of Certain Shrimp and Shrimp Products*, ¶ 129, WT/DS58/AB/R (Oct. 12, 1998).

⁵ See Int’l Law Comm’n’s Draft Articles on Responsibility of States for Internationally Wrongful Acts, U.N. GAOR, 56th Sess., Supp. No. 10 at ch. 4, U.N. Doc. A/56/10, Article 33 (2001). The International Law Commission first formally adopted necessity as a defense in 1980 as part of its 32d Session Reports on State Responsibility. *Id.*

1. Necessity may not be invoked by a State as a ground for precluding that wrongfulness of an act not in conformity with an international obligation of that State unless the act:

(a) is the only way for the State to safeguard an essential interest against a grave and imminent peril; and

(b) does not seriously impair an essential interest of the State or States towards which the obligation exists, or of the international community as a whole.

2. In any case, necessity may not be invoked by a State as a ground for precluding wrongfulness if:

(a) the international obligation in question excludes the possibility of invoking necessity; or

(b) the State has contributed to the situation of necessity.⁶

Since a plea of necessity precludes any *wrongfulness* as a result of derogating from international obligations, it is applied only in very exceptional and limited circumstances.⁷ By framing the plea of necessity in the negative rather than the affirmative, the opening words of the Draft Article on necessity emphasize its exceptional character.⁸

It follows that a state of necessity refers to a situation in which the only means available to a State to safeguard an essential interest threatened by a grave and imminent peril is to adopt conduct not in conformity with its international obligations.⁹ A state of necessity therefore contemplates the "safeguarding an essential interest" of a State, rather than the protection of a State's "very existence."¹⁰ Thus, whether or not the State will not survive without the action taken inconsistently with a binding international obligation is not relevant in determining whether an essential

⁶ *Id.*

⁷ *See id.*

⁸ *See id.*

⁹ *Thirty-Second Session Report, supra* note 1, art. 33.

¹⁰ *See id.* art. 25, §1(a); *see also* Roberto Ago, *Addendum to the Eighth Report on State Responsibility*, U.N. Doc. A/CN.4/318/ADD/5-7, *reprinted in* [1980] 2 Y.B. Int'l L. Comm'n, pt. 1, 13, 19, ¶ 12, U.N. Doc. A/CN.4/SER.A/1980/Add.1 (Part 1) [*hereinafter Ago Report*]; *see also* Case Concerning the Gabčíkovo-Nagymaros Project (Hung v. Slov), *supra* note 3, at 71-73. (reaffirming the use of the essential interests standard as opposed to the traditional doctrine of necessity however, rejecting its applicability under the circumstances of the case presented).

interest is at stake.¹¹ The essential interest must be of an exceptional nature in order to excuse violations of international law.¹²

Invoking a state of necessity also implies that a State is aware of its decision not to act in conformity with an international obligation.¹³ In its explanation of the plea of necessity, the International Law Commission (ILC) has not set forth specific situations that would constitute an essential interest. This is probably because the commission recognizes that whether an essential interest is present depends almost entirely on the circumstances unique to each individual case.¹⁴ In the Addendum to the Eighth Report on State Responsibility,¹⁵ Mr. Roberto Ago provides examples of situations which would likely constitute an essential interest: (1) political and economic survival; (2) the continued functioning of essential State services; (3) maintenance of internal peace; (4) survival of a sector of the State's population; and (5) preservation of the environment.¹⁶ Another example is "the existence of grave and imminent danger to the State, to some of its nationals or simply to human beings."¹⁷

¹¹ See Ago Report, *supra* note 10, at 19, ¶ 12.

¹² *Id.*

¹³ The British government has expressed reservations about the state of necessity being recognized under the ILC's Draft Articles since such recognition would promote lawlessness and undermine the rule of law in international relations. However, the United Kingdom noted in its objections that:

[A]ll the same that further consideration is required as to whether there is a need for a provision concerning action taken by a State to cope with environmental emergencies which pose an immediate threat to its territory (as envisaged in the Commentary, 97-02583, p. 246 paragraph 16). If so, this would be akin to *force majeure* or distress.

See DRAFT ARTICLES ON STATE RESPONSIBILITY: COMMENTS BY THE UNITED KINGDOM GOVERNMENT (1998), <http://icil.law.cam.ac.uk/ILCSR/UK.rtf>.

¹⁴ *Thirty-Second Session Report*, *supra* note 1, ¶ 3; see also Boed, *supra* note 4, at 15.

¹⁵ See Ago Report, *supra* note 10, at 19, ¶ 12.

¹⁶ *Id.*

¹⁷ ILC 53rd Report at paragraphs 12 and 13 notes that the plea of necessity may apply to "ensur[e] the safety of civilian population." Draft Articles on Responsibility of States for Internationally Wrongful Acts, in Report of the Intern'l Law Comm'n on the Work of Its Fifty-third Session, U.N. GAOR, 56th Sess., Supp. No. 10 at 43, U.N. Doc. A/56/10 (2001), available at <http://www.un.org/law/ilc/reports/2001/2001report.htm>; see also Ian Johnson, *The Plea of Necessity in International Legal Discourse: Humanitarian*

In light of the foregoing examples, necessity denotes those exceptional cases where the only way a State can safeguard an essential interest threatened by a grave and imminent peril is by violating an international legal obligation that would, in that instance, be considered of lesser weight.¹⁸ An essential interest can be an interest of one particular State, or it can be an interest of the international community as a whole. However, an essential interest claim rarely succeeds to excuse or preclude wrongfulness arising from a violation of an international obligation. The plea of necessity is not available to preclude responsibility for violations of *jus cogens* norms.¹⁹

One historical example that is continually used as precedent involves the *Russian Fur Seals* controversy in which the international obligation in question required States to not sail in an area of the high seas.²⁰ The protection of the natural environment was the essential interest asserted. In other words, the Russian government claimed that preventing the extinction of seals was an essential interest.²¹ To accomplish this objective, the Russian government issued a decree prohibiting both the United States and England from sailing in an area of the high seas.²² This decree was promulgated because Russia believed that there was an "absolute necessity" to protect against the extinction of the seals in this area of the high seas.²³ In this instance, the Russian government was held to have satisfied the requirements of necessity.²⁴ Notably, the threat was made more imminent by the

Intervention and Counter Terrorism, 43 COLUM. J. TRANSNAT'L L. 337 (2005).

¹⁸ See Draft Articles, *supra* note 5, art. 25, §1(a).

¹⁹ See *infra* note 58; see also ILC 53rd Report, *supra* note 17, at 49, art. 25, ¶ 2(a) (noting that necessity may not be provoked if the international obligation in question excludes the possibility of invoking necessity).

²⁰ See *Ago Report*, *supra* note 10, at 27, ¶ 33 (citing "*Force majeure*" and "*fortuitous event*" as *Circumstances Precluding Wrongfulness: Survey of State Practice, International Judicial Decisions and Doctrine*, ¶ 155, U.N. Doc. A/CN.4/315 (1977), reprinted in [1978] 2 Y.B. Int'l L. Comm'n pt. 1, 61-228, U.N. Doc. A/CN.4/SER.A/1978/Add.1 (Part 1)).

²¹ See *Ago Report*, *supra* note 10.

²² *Id.* (explaining that this is a violation of international law because areas of "high seas" are not under the jurisdiction of any one individual government; therefore, the Russian government did not have the authority to prohibit sailing).

²³ See *id.* at 27, ¶ 33.

²⁴ The imminent nature of the threat was the approaching hunting season. The

approaching seal hunting season, which would have to be foregone had the seals become extinct.

The 1967 *Torrey Canyon* incident also satisfied the requirements of necessity.²⁵ *Torrey Canyon* involved a Liberian oil tanker carrying 117,000 tons of crude oil.²⁶ After hitting submerged rocks, the tanker began spilling oil into areas outside British territorial waters.²⁷ The British government attempted a number of times to resolve the oil spill to prevent damage to their coastline.²⁸ Unfortunately, the tanker split into three pieces prior to the successful abatement of the danger, resulting in even more oil being spilled into the waters.²⁹ Consequently, the British government made the decision to prevent more spillage by bombing the tanker in order to burn the oil still present on the vessel.³⁰ After the bombing, it was determined that the British government's actions satisfied the requirements to invoke necessity, specifically because the threat was one of extreme danger and the government attempted all other means to prevent further damage.³¹ Therefore, Britain was held not to have acted inconsistently with its international legal obligations by bombing a tanker outside its jurisdiction because the bombing was justified under the defense of necessity.³²

In the more contemporary decision of the *Legal Consequences of the Construction of a Wall in the Occupied Palestinian Territory*, the International Court of Justice (ICJ) disagreed with

threat to nature was exceptional because of the high likelihood of the extinction of seals in the region and the impossibility of averting this threat through other means. Therefore, the ban on seafaring in this area of the Ocean was in effect to ensure that the hunting season was going to commence by averting the extinction of the seals. *Id.*

²⁵ See *id.* at 28, ¶ 35 (citing 281 PARL. DEB., H.L. (5th ser.) (1967) 874-883).

²⁶ *Id.*

²⁷ *Ago Report*, *supra* note 10.

²⁸ *Id.* (explaining that the British government began using detergents with the hope that it would help to disperse the oil which had spread over the surface of the sea, and after that failed, they hired a salvage team to try and resurface the tanker).

²⁹ *Id.*

³⁰ *Id.*

³¹ See *id.* at 28, ¶ 35.

³² *Id.* (explaining that after the bombing, the United Nations responded by stating that any actions taken that are similar to bombing another country's ship on international waters must be proportionate to the threat posed).

the Israeli government's argument that necessity justified the construction of a wall which ultimately forced hundreds of thousands of Palestinians to live in "completely encircled communities."³³ According to the ICJ, the Israeli government failed to demonstrate necessity because the act of building a wall, "is [not] the only way for the State to safeguard an essential interest against a grave and imminent peril."³⁴ Moreover, the ICJ noted that Israel's essential interest was inferior to its duty to conform to international obligations and that Israel's interests lacked the gravity and imminence required to invoke a plea of necessity. The ICJ agreed that Israel has a duty to protect the life of its citizens, since the preservation of human life from violent terrorist attacks was an essential interest.³⁵ However, the ICJ still held that Israel must act in conformity with all its international obligations.³⁶

In the *Gabcikovo-Nagymaros* case, Hungary attempted to justify its breach of a 1977 treaty with Czechoslovakia on the basis of ecological necessity. Hungary argued that the locks and dam project on the Danube River posed hazardous risks to the local environment.³⁷ The ICJ recognized that the concerns expressed by Hungary with regard to preserving the local environment from ecological devastation related to an essential State interest, but ultimately dismissed the plea of necessity because it found that Hungary had contributed to the conditions under which it was led to invoke the necessity defense.³⁸

In the *M/V 'Saiga' (No.2) Case*, the International Tribunal of the Law of the Sea (ITLS) found that in order to invoke the plea of necessity, the essential interest advanced by a State must be in

³³ See *Legal Consequences of the Construction of a Wall in the Occupied Palestinian Territory*, 2004 I.C.J. LEXIS 20, 82 [hereinafter *Palestinian Territory*].

³⁴ See *id.* at 139 (citing Draft Articles, *supra* note 5, at §1(a)).

³⁵ See *Palestinian Territory*, *supra* note 33, at 140.

³⁶ *Id.*

³⁷ *Case Concerning the Gabcikovo-Nagymaros Project*, *supra* note 35 at 41-42.

³⁸ *Id.* note 5 at 129. "[Hungary required suspension as a prior condition of environmental investigation because it claimed continuation of the work would prejudice the outcome of negotiations.] In this regard it cannot be left out of consideration that Hungary itself, by suspending the works at Nagymaros and Dunakiliti, contributed to the creation of a situation which was not conducive to the conduct of fruitful negotiations." *Id.*

grave and imminent peril.³⁹ In this case, an oil tanker from St. Vincent and the Grenadines was arrested by Guinean customs patrol boats after supplying oil to some fishing vessels in parts of the Exclusive Economic Zone of Guinea.⁴⁰ The ITLS held the arrest to be wrongful because Guinea applied its own customs laws to an area outside its exclusive zone.⁴¹ Guinea appealed by relying on the plea of necessity, arguing that maximizing tax revenues was an essential State interest.⁴² The Tribunal agreed that this was an essential State interest but dismissed the necessity plea, holding that Guinea had failed to show that there were no less intrusive means to safeguarding such an interest and how its interest in maximizing tax revenue was in grave and imminent peril.⁴³

A. Summary of the Preconditions for Relying on a Plea of Necessity: Essential Interest

As noted above, the measures taken by a State under a plea of necessity must be focused towards protecting an essential interest. In addition, the circumstances under which an essential interest may arise depend on the circumstances of each particular case. The variety of instances that may rise to an essential interest, as previously alluded to, may be why the ILC has declined from listing the circumstances under which a plea of necessity may arise.⁴⁴ Thus, although there is yet to be a case finding that the long term health of a State's population is an essential interest, under the prevailing circumstances of the HIV/AIDS pandemic in a variety of sub-Saharan African countries, this plea is arguably available. In fact, if we were to argue by analogy, the circumstances under which the plea has been accepted in previous cases strongly suggests that the long term health of a State's population is an essential interest. Based on the precedents discussed in the previous section, necessity was invoked to

³⁹ M/V 'Saiga' (No. 2) (St. Vincent v. Guinea), 120 I.L.R. 143 (Int'l Trib. L. of the Sea 1999) [hereinafter M/V Saiga].

⁴⁰ *Id.* at 1335-36.

⁴¹ *Id.*

⁴² *Id.*

⁴³ *Id.*

⁴⁴ *Thirty-Second Session Report*, *supra* note 1, art. 33, ¶ 31.

preclude wrongfulness for violation of an international obligation where the essential interest was environmental protection or ecological preservation and ensuring the safety of a civilian population.⁴⁵ The fact that the plea of necessity was successful in these cases indicates that under international law, ensuring the safety of a civilian population, and environmental protection all constitute essential interests.⁴⁶

In addition, based on recent jurisprudence regarding what constitutes an essential interest, the invocation of necessity seems to hinge upon a combination of both the imminence of the threat to the essential interest and the availability of less intrusive relief.⁴⁷ According to a leading commentator and rapporteur of the 2001 Draft Articles on State Responsibility, the threat must be "objectively established and not merely apprehended as possible."⁴⁸ In the *Gabcikovo-Nagymaros* case, the ICJ argued that a grave peril appearing in the long term may still be imminent if the realization of the peril, "however far off it might be, is not thereby any less certain and inevitable."⁴⁹ The 2001 ILC

⁴⁵ *Ago Report*, *supra* note 10, at 19, ¶ 12; *see also supra* note 17.

⁴⁶ Despite the fact that the question of necessity is dependent upon objectively viewed circumstances, a question still arises as to whether an essential interest can be automatically determined. States must be permitted to determine for themselves what constitutes an essential interest. To claim otherwise, that the State must seek outside determination as to what their essential interests are, defies logic. The State involved is the one in the best position to make such a determination. Since an essential interest cannot be prejudged, the state involved must make this determination based upon all attending circumstances. Article 31(b) of the TRIPS Agreement permits states to determine if an emergency exists. This position is further confirmed by the Doha Declaration on TRIPS and Public Health in its recognition that HIV/AIDS, tuberculosis, malaria, and other pandemics are all instances of public health crises that can represent national emergencies or other circumstances of extreme urgency. *See Declaration on the TRIPS Agreement and Public Health*, WT/MIN(01)/Dec/2 P4 (Nov. 14, 2001), http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.pdf; *see also* James Thuo Gathii, *The Legal Status of the Doha Declaration on Trips and Public Health Under the Vienna Convention on the Law of Treaties*, 15 HARV. J. LAW & TECH. 291 (2002)

⁴⁷ *See Draft Articles*, *supra* note 5

⁴⁸ JAMES CRAWFORD, *THE INTERNATIONAL LAW COMMISSION'S ARTICLES ON STATE RESPONSIBILITY: INTRODUCTION, TEXT AND COMMENTARY*, 183 (2002); *see Declaration on the TRIPS Agreement and Public Health*, *supra* note 46; *see also* Gathii, *supra* note 46.

⁴⁹ *Draft Articles*, *supra* note 5, at 42.

Commentary reiterated this finding that a “measure of uncertainty about the future does not necessarily disqualify a state from invoking necessity, if the peril is clearly established on the basis of the evidence reasonably available at the time.”⁵⁰

The interest protected by the international obligation breached on the basis of necessity must also be inferior to the threatened State’s essential interest.⁵¹ The jurisprudence on essential State interests therefore indicates that economic or monetary interests of a State are generally less significant to other essential interests, such as long term humanitarian and ecological interests.⁵²

B. Grave and Imminent Peril

An objective standard is used when determining the imminence of the peril threatening an essential interest; to invoke, necessity presupposes something “truly extreme and irresistible.”⁵³ As noted above, a peril on the far long term horizon may still be considered grave and imminent.⁵⁴ In cases of necessity, the peril has not yet occurred, so there may be different views or uncertainty as to the gravity and imminence of the peril. However, a measure of uncertainty about the future does not rule out the existence of necessity.

The critical factor is that the peril be both extremely grave and a threat to the essential interest at the actual time. Moreover, the peril must not have been escapable by any other means, even a more costly alternative that could be adopted in compliance with the international obligations in question.⁵⁵ A threat must also be imminent. The ILC’s draft commentary is ambiguous regarding what is meant by imminence or actual time. However, it is plausible to make the case that all that is required to show

⁵⁰ CRAWFORD, *supra* note 48, at 184 (citing ICJ REPORTS 1997, p. 7, at 42, ¶ 54).

⁵¹ See *Thirty-Second Session Report*, *supra* note 1, art. 33 (stating that a plea of necessity must “not seriously impair an essential interest of the State [or States] towards which the obligation existed.”).

⁵² See *M/V Saiga*, *supra* note 39 (holding that a State’s interest in tax revenues was not superior to the interest in maintaining the status quo in the multilateral obligation).

⁵³ *Summary Records of 1613th Meeting, State Responsibility (continued)*, U.N. Doc. A/CN.4/318Add.5 and 6, A/CN.4/328 and Add.1-4 (1980), reprinted in [1980] 1 Y.B.Int’l L. Comm’n 158, U.N. Doc. A/CN.4/SER.A/1980.

⁵⁴ See Draft Articles, *supra* note 5.

⁵⁵ ILC 53rd Report, *supra* note 17, ¶ 33.

imminence is a demonstration that failure to act immediately will undeniably lead to catastrophe in the future. In other words, a threat that is guaranteed to materialize at some future unknown date would be imminent on the premise that if nothing is done, a catastrophe is likely to occur.⁵⁶

C. *Contribution and Jus Cogens*

As noted above, a State cannot rely on the plea of necessity to preclude a violation of an international obligation if it deliberately or inadvertently provoked the existence of such necessity.⁵⁷ The plea of necessity is also unavailable where the obligation sought to be excused is a *jus cogens* norm or where the obligation precludes the existence of such a plea of necessity.⁵⁸

D. *The Obligations of the TRIPS Agreement*

Article 27(1) of the TRIPS Agreement provides that signatory States are obliged to protect "any inventions, whether products or processes, in all fields of technology, provided they are new, involve an inventive step and are capable of industrial application."⁵⁹ Article 28 of TRIPS confers upon patent holders the exclusive rights to "prevent third parties not having the owner's consent from the acts of: making, using, offering for sale, selling or importing" patented products.⁶⁰

The TRIPS Agreement also provides for limited exceptions if

⁵⁶ CASS SUNSTEIN, *LAWS OF FEAR* 18 (2005). Remarkably, he suggests that catastrophe would have to be something akin to the elimination of the entire species rather than simply a few. Such a high standard for catastrophe sets an extremely high standard for invoking precaution at all. *Id.* For a review of Sunstein's arguments in this book, please see Gregory Mandel & James Gathii, *Cost Benefit Analysis and the Precautionary Principle: Beyond Cass Sunstein's Laws of Fear*, ILL. L. REV. (forthcoming 2006).

⁵⁷ See ILC 53rd Report, *supra* note 17, at 49, art. 25, ¶ 2(b) (noting plea of necessity is precluded if the state has contributed to the situation of necessity).

⁵⁸ See *id.* at 49, art. 25, ¶ 2(a) (noting that necessity may not be provoked if the international obligation in question excludes the possibility of invoking necessity).

⁵⁹ Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, Legal Instruments - Results of the Uruguay Round vol. 31, 33 I.L.M. 81 (1994), art. 27§1 [hereinafter TRIPS].

⁶⁰ *Id.* at art. 28 §1(a).

consistent with the “normal exploitation of the patent.”⁶¹ After following an elaborate set of conditions contained in Article 31, the Doha Declaration on TRIPS and Public Health, and the December 2005 Decision of the TRIPS Council (now a proposed Amendment to TRIPS), WTO members may use the subject matter of a patent without the authorization of a patent holder.⁶²

The TRIPS Agreement gives patent holders a twenty-year period to possess exclusive rights to the profits of their investment in drug research and development without the requirement to provide preferential access to the drugs for low-income populations.⁶³ In contrast, in the United States under the Constitution’s patent and copyright clauses, the private benefit of intellectual property rights is guaranteed to the extent that it supports the public use of the information needed by scientists, teachers, students, business people, librarians, and others.⁶⁴

The flexibility contained in Articles 7 and 8 of the TRIPS Agreement, the Doha Declaration on TRIPS, the November 2001 Public Health Decision, and the proposed Article 31 *bis* Amendment to the TRIPS Agreement while important, have proved to be illusory.⁶⁵ This is particularly because of the

⁶¹ *Id.* at art. 30. Article 30 provides the following: “Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.” *Id.*

⁶² See Declaration on the TRIPS Agreement and Public Health, *supra* note 46; Gathii, *supra* note 46.

⁶³ TRIPS, *supra* note 59, art. 33.

⁶⁴ See U.S. Const. art. I, 8, cl 8 (promoting “the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries”). See generally James Thuo Gathii, *Construing Intellectual Property Rights and Competition Policy Consistently with Facilitating Access to Affordable Aids Drugs to Low-end Consumers*, 53 FLA. L. REV. 727, 747 (2001) (discussing “The Dialectical Character of Private Property Rights under TRIPS”).

⁶⁵ Heinz Klug, *Comment: Access to Essential Medicines – Promoting Human Rights Over Free Trade and Intellectual Property Claims*, in INTERNATIONAL PUBLIC GOODS AND TRANSFER OF TECHNOLOGY UNDER GLOBALIZED INTELLECTUAL PROPERTY REGIME 481, 490 (Keith Maskus & Jerome Reichman eds., 2005) (citing Carlos M. Correa, *Implications of the Doha Declaration on the TRIPS Agreement and Public Health, Health Economics and Drugs* (World Health Org., EDM Series No.12, WHO/EDM/PAR/2002.3, June 2002); Carlos M. Correa, *Implementation of the WTO General Council Decision on Paragraph 6 of the Doha Declaration on Trips and Public*

implausibility of the contemplated compulsory licensing preconditions. The use of the threat of economic sanctions by the United States under its special Section 301 powers, in addition to other types of pressures, have assured that the States that most desperately need access to essential medicines are unable to obtain them.⁶⁶

My argument is that while the currently available antiretroviral drugs under patent are the only known treatments for those suffering from the virus, the plea of necessity is available to enable these countries to break the patents—inconsistent with the requirements of the TRIPS Agreement Articles 27-31—as long as the following are also true: (1) these medicines are intended exclusively for indigent persons and (2) such provisioning is part of a comprehensive program addressing as many aspects of the pandemic as possible. In addition, even if the TRIPS Agreement is amended with Article 31 *bis*, there is no guarantee that the United States or other WTO member countries will forfeit their right to protest the inconsistency of the Amendment and the provisions of the TRIPS Agreement that safeguard patent rights. It is therefore a positive step to develop a variety of credible legal arguments, such as the defense of necessity, in favor of compulsory licensing.

E. Applying the Plea of Necessity to the HIV/AIDS Pandemic in Sub-Saharan Africa: Essential Interest

Sub-Saharan Africa is the epicenter of the HIV/AIDS pandemic.⁶⁷ By 2002, more than 15 million people had lost their

Health (2003) (unpublished draft). See also Frederick Abbott, "The WTO Medicines Decision: World Pharmaceutical Trade and the Protection of Public Health," 99 AM. J. INT'L L. 317 (2005); Peter K. Yu, *The International Enclosure Movement*, 82 IND. L.J. (forthcoming 2007) (arguing that Article 31 *bis* does not allow less developed countries to reclaim their lost policy space).

⁶⁶ The United States is unhappy that African countries pushing for access to essential medicines want to reopen the TRIPS Agreement. See *U.S., Others Slam African Proposal for Medicines Agreement in TRIPS Accord*, 21 INT'L TRADE REP. 48, 1934 (2004); see also James Thuo Gathii, *The Structural Power of Strong Pharmaceutical Patent Protection in U.S. Foreign Policy*, 7 J. GENDER RACE & JUST. 267 (2003).

⁶⁷ UNAIDS, *Report on the Global HIV/AIDS Epidemic*, 22, UNAIDS/02.26E (July 2002), http://data.unaids.org/Global-Reports/Barcelona/BRGlobal_AIDS_Report_en.pdf. For more on the severity of the crisis, see GREG BEHRMAN, *THE INVISIBLE PEOPLE: HOW*

lives to the disease or health complications associated with it since the pandemic emerged in the 1980's.⁶⁸ In 2005 alone, an estimated 2.4 million adults and children died as a result of HIV/AIDS in sub-Saharan Africa.⁶⁹ Currently, in excess of 25.8 million Africans are living with the disease.⁷⁰ Infection rates vary by country, but they are highest in Southern Africa.⁷¹ Infection rates have reached 37.3% in Botswana; 38.8% in Swaziland; and 28.9% in Lesotho.⁷² South Africa continues to have a prevalence rate of around 20%.⁷³ Dramatic rises in infection rates in Southern Africa as well as the sharp increases in the occurrence of HIV among pregnant women in Cameroon (doubling to over 11% among those aged 20-24 between 1998 and 2000) shows how suddenly the pandemic can surge.⁷⁴

By December 2005, women accounted for about 46% of all adults living with HIV infections worldwide, and 57% for those in sub-Saharan Africa.⁷⁵ As a result of the pandemic, life expectancy in the most affected countries has reduced dramatically and there are over 12 million AIDS orphans in sub-Saharan Africa alone.⁷⁶ There has already been a noticeable decline in school enrollment

THE U.S. HAS SLEPT THROUGH THE GLOBAL AIDS PANDEMIC, THE GREATEST HUMANITARIAN CATASTROPHE OF OUR TIME (2004); STEPHEN LEWIS, RACE AGAINST TIME, CBC MASSEY LECTURE SERIES (2005); OBIJIOFOR AGINAM, GLOBAL HEALTH GOVERNANCE: INTERNATIONAL LAW AND PUBLIC HEALTH IN A DIVIDED WORLD (2005).

⁶⁸ See Avert.org, *The Impact of HIV & AIDS on Africa*, Nov. 24, 2005, <http://www.avert.org/aidsimpact.htm>; see also *Report on the Global HIV/AIDS Epidemic*, *supra* note 67, at 22 (reporting that 20 million have lost their lives to the epidemic since 1980).

⁶⁹ UNAIDS & WHO, *AIDS Epidemic Update*, 80, UNAIDS/05.19E (Dec. 2005), http://www.unaids.org/epi/2005/doc/EPIupdate2005_pdf_en/epi-update2005_en.pdf.

⁷⁰ Jenni Fredricksson & Annabel Kanabus, *HIV & AIDS in Africa*, AVERT ORG., Jan. 16, 2006, <http://www.avert.org/aafrica>; see also UNAIDS, *Report on the Global HIV/AIDS Epidemic*, 124, UNAIDS/00.13E (June 2000), http://data.unaids.org/Global-Reports/Durban/Durban_Epi_report_en.pdf.

⁷¹ *Report on the Global HIV/AIDS Epidemic*, *supra* note 67, at 8.

⁷² See Fredericksson & Kanabus, *supra* note 70.

⁷³ *Id.*

⁷⁴ See *id.*

⁷⁵ *AIDS Epidemic Update*, *supra* note 69, at 4.

⁷⁶ UNAIDS, UNICEF & USAID, *Children on the Brink 2004: A Joint Report of New Orphan Estimates and a Framework for Action*, 3 (July 2004).

as a result of the pandemic.⁷⁷ This will negatively affect the ability of sub-Saharan African countries to meet the education targets contained in the Millennium Development Goals.⁷⁸ In some countries life expectancy has been cut in half.⁷⁹ For example, in Zimbabwe life expectancy will decline from 71.4 years before the pandemic to 34.6 years in 2010.⁸⁰ Since those infected are usually in the productive years of their lives, economic progress has slowed.⁸¹ In some rural areas, labor shortage in agriculture is already threatening food security as a result of the mortality rates related to the HIV/AIDS pandemic.⁸²

The extent of the pandemic is stretching health resources way beyond capacity. There is no public health system anywhere in the world, least of all in sub-Saharan Africa, which could handle the vast numbers of those infected individuals. In many countries, those with the infection predominantly occupy the hospital beds.⁸³ The heavy burden on the already poorly funded health system in many sub-Saharan African countries has led to lower levels of care.⁸⁴ As a result, a huge burden of caring for the sick is now on the hands of families, especially those that cannot afford to pay for long hospital stays to permit diagnosis of this increasingly complex and pervasive pandemic.⁸⁵ There are also fewer health

⁷⁷ The World Bank, *Education and HIV/AIDS: A Window of Hope*, 4, http://www1.worldbank.org/education/pdf/Ed%20&%20HIV_AIDS%20cover%20print.pdf (May 2002). Infection rates among teachers is as high as 19% of men and about 29% of women in Zimbabwe. See *The Impact of HIV & AIDS on Africa*, *supra* note 68.

⁷⁸ *Education and HIV/AIDS*, *supra* note 77, at 8 (discussing as a result of the epidemic, children are less likely to attend school, either because they themselves are infected or because they were retained at home to take care of patients; this makes it increasingly hard for African countries to attain education targets set forth in the Millennium Development Goals).

⁷⁹ See generally *The Impact of HIV & AIDS on Africa*, *supra* note 68. A comparison table lists the life expectancy before the epidemic and the estimate by 2010. For instance, Botswana's life expectancy will drop from 74.4 to 26.7, Namibia 68.8 to 33.8, Swaziland from 74.6 to 33. *Id.*

⁸⁰ See *id.*

⁸¹ See *id.*

⁸² See *id.* (discussing the HIV/AIDS impact on labor supply through increased mortality and morbidity).

⁸³ See *id.*

⁸⁴ *The Impact of HIV & AIDS on Africa*, *supra* note 68.

⁸⁵ See Fredericksson & Kanabus, *supra* note 70.

professionals willing to take on the increased workload and burden of caring for infected patients.⁸⁶ Some sub-Saharan African countries have had 5 to 6 fold rises in the illness and death rates of the health care workforce.⁸⁷ Family dissolution as a result of a parent, in particular a mother, dying from HIV infection is now a norm in 65% of Zambian households.⁸⁸ The pandemic robs those left behind of caretakers and breadwinners.⁸⁹

Progress in poverty reduction programs has been adversely undermined by the spread of the infection. A study in Burkina Faso, Rwanda, and Uganda found that the pandemic not only reversed progress in poverty reduction but will increase the percentage of those living in extreme poverty from 45% in 2000 to 51% in 2015.⁹⁰ In South Africa, a study found that families with a HIV infected member also experienced a reduction in income and a concomitant reduction in the amount of money spent on necessities including food.⁹¹

The pandemic is also affecting productivity in the private sector. Costs related to the pandemic include absenteeism, as well as increased health care, recruitment, and training costs— all of which result in declines in profitability.⁹² Some companies have begun prevention and treatment programs for their workers, but the pandemic's impact on the economies of these countries is undermining their abilities to effectively address the consequences of the virus.⁹³

⁸⁶ See Rob Noble, *HIV and AIDS in Zambia the Epidemic and Its Impact*, AVERT ORG., <http://www.avert.org/aids-zambia.htm>.

⁸⁷ See Fredericksson & Kanabus, *supra* note 70.

⁸⁸ Noble, *supra* note 86.

⁸⁹ See Fredericksson & Kanabus, *supra* note 70.

⁹⁰ See *id.*

⁹¹ See MALCOLM STIENBERG ET AL, HITTING HOME, HOW HOUSEHOLDS COPE WITH THE IMPACT OF HIV/AIDS EPIDEMIC (2002), <http://www.kff.org/southafrica/upload/Hitting-Home-How-Households-Cope-with-the-Impact-of-the-HIV-AIDS-Epidemic-Report.pdf>; see also *The Impact of HIV and Aids on Africa*, *supra* note 68.

⁹² Markus Haacker, *The Economic Consequences of HIV/AIDS in Southern Africa*, (IMF Working Paper, Africa Department WP/02/38 2002), available at <http://www.imf.org/external/pubs/ft/wp/2002/wp0238.pdf>.

⁹³ Simon Dixon et al., *The Impact of HIV/AIDS on Africa's Economic Development*, 324 BRIT. MED. J. 232, 232-34, (2002); Mead Over, *The Macroeconomic Impact of AIDS in Sub-Saharan Africa* (World Bank Technical Working Paper No. 3, 1992), <http://www.worldbank.org/aids-econ/macro.pdf>.

These and other effects of the pandemic clearly amount to an essential State interest for the purpose of invoking the plea of necessity. I contend that for all the foregoing reasons, the long term health of a country's population in which there is a high prevalence of a pandemic such as HIV/AIDS certainly qualifies as an essential State interest. Unsurprisingly, the World Health Organization (WHO) also considers the foregoing circumstances to constitute an emergency. According to the WHO, lack of access to antiretroviral treatment is a global health emergency.⁹⁴ The WHO defines an emergency as "a sudden occurrence demanding immediate action that may be due to epidemics, to natural or technological catastrophes, to strife or to other man-made causes."⁹⁵ Some observers have however noted that an emergency is not a precondition for engaging in compulsory licensing under the TRIPS Agreement.⁹⁶ This is consistent with the 2001 Declaration on TRIPS and Public Health.⁹⁷ Whether an emergency is a prerequisite, the foregoing discussion indicates that the essential interests of countries with a high rate of HIV/AIDS infection could argue that necessity may preclude them from bearing responsibility for engaging in compulsory licensing if they could also show that they stood to suffer grave and imminent peril.

The WHO's definition of an emergency seems consistent with the observations of James Crawford, the ILC's 2001 Rapporteur

⁹⁴ See World Health Organization, *HIV/AIDS treatment and care: WHO Protocols for CIS Countries*, [www.http://euro.who.int/document/e83863.pdf](http://euro.who.int/document/e83863.pdf); World Health Organization, *WHO Says Failure to Deliver AIDS Medicines is a Global Health Emergency* (2003), http://whqlibdoc.who.int/press_release/2003/PR_67.pdf (providing that "failure to deliver antiretroviral treatment for AIDS to the millions of people who need it is a global health emergency").

⁹⁵ See World Health Organization, *Coping With Major Emergencies: WHO Strategy and Approaches to Human Action* (1995), http://whqlibdoc.who.int/hq/1995/WHO_EHA_95.1.pdf (defining emergency).

⁹⁶ See James Love, *Not True That Public Health Emergencies Necessary for Compulsory Licenses of Patents*, Nov. 29, 2005, <http://mistakesaremade.blogspot.com/2005/11/not-true-that-public-health.html> (citing World Health Organization, *Compulsory Licensing of Pharmaceuticals and TRIPS* (Oct. 2005), http://www.wto.org/english/tratop_e/trips_e/public_health_faq_e.html, recognizing that the 2001 Doha Declaration on TRIPS and Public Health noted that countries could automatically determine when to engage in compulsory licensing).

⁹⁷ World Trade Organization, Ministerial Declaration of 14 November 2001, WT/MIN(01)/DEC/2, http://www.wto.org/English/thewto_e/minist_e/min01_e/mindecl_trips_e.htm [hereinafter Doha Declaration].

on State Responsibility, who noted that long term predictions and prognoses are particularly pertinent to questions concerning threats to essential interests.⁹⁸ Further, the right to life—including increasing life expectancy and decreasing infant mortality rates—has been dubbed the “supreme right” from which no derogation is permitted.⁹⁹ The health of a people has a tremendous impact on all other facets of their life. Economic development and social order are closely linked to the health of the population.¹⁰⁰ The extent and impact of the HIV/AIDS pandemic in sub-Saharan Africa strongly suggests that the health and survival of citizens in the affected States rises to an essential interest.

An essential interest also requires that it be superior to the interest of other states that would be adversely affected by the breach of the obligation.¹⁰¹ In my view, the long term health interests of the population of African countries should be given more weight than the property rights interests that would be injured by compulsory licensing of essential medicines. As I noted before, my argument here is not based on a tradeoff between health and patent rights; rather, I proceed on the premise that in the countries where the HIV/AIDS pandemic has had devastating social, economic, and other consequences, a case for limited and targeted compulsory licensing can be made. Moreover, my claim is that—in balancing between the preservation of human lives of those afflicted by the pandemic against the economic interests of developed countries in preserving patents—the balance ought to tilt towards preserving and protecting human life.¹⁰²

⁹⁸ See CRAWFORD, *supra* note 48, at 506.

⁹⁹ See U.N. Off. High Comm. Hum. Rts. *General Comment to Article 6 ICCPR Conv.* 30/04/82 (16th sess. 1982); see also James Thuo Gathii, *Rights, Patents, Markets and the Global AIDS Pandemic*, 14 FLA. J. INT'L L. 261-352 (2002); *Ethics and the Pharmaceutical Industry* (Michael Santoro & Thomas Gorrie eds., 2005) (covering some of the human rights issues raised by patent protection); see also, Jamie Crook, *Balancing Intellectual Property With the Human Right to Health*, 23 BERKELEY J. INT'L L. 524 (2005)

¹⁰⁰ See World Development Report 1993, *Investing in Health*, http://www-wds.worldbank.org/servlet/WDSCContentServer/WDSP/IB/1993/06/01/000009265_3970716142319/Rendered/PDF/multi0page.pdf.

¹⁰¹ See *Thirty-Second Session Report*, *supra* note 1, art 34.

¹⁰² In *MV Saiga*, the Tribunal found Guinea's interest in maximizing tax revenues to be inferior to its duties under the exclusive economic zone obligations. *MV Saiga*, *supra* note 39. In an important new article, Madhavi Sunder argues in favor of a theory

It is of course important to acknowledge that the resources invested in research and development results in the creation of new and useful products or processes, like pharmaceuticals, that are generally beneficial to the public health. In the pharmaceutical industry, this is particularly important as increased resources dedicated to research and development lead to the creation of new drugs and treatments for the illnesses plaguing the world today.¹⁰³ Thus, patent protection is considered an essential interest of both the States subject to the TRIPS agreement, as well as the international community as a whole. However, the positive correlation between patents and drug development is difficult to demonstrate for diseases such as the HIV/AIDS pandemic that affect populations that can hardly afford name brand drugs.

Since necessity will always involve a conflict between the current situation within a State—such as that involving a public health pandemic—and its international obligations to respect patent protections under the TRIPS Agreement, fulfilling the essential interest condition involves a balancing test between competing interests. A State acting to protect an essential interest can only do so as long as it does not “seriously impair” an essential interest of another State.¹⁰⁴ In other words, if the essential interest of a State invoking necessity outweighs the essential interest of other States, this condition is met.

Ultimately, my claim is that in light of the impact of the HIV/AIDS pandemic, it is credibly arguable that the lives of those involved, as well as the long term health impact, need to be balanced against the patent rights of pharmaceutical companies.

of intellectual property that accommodates the full range of human values implicit in intellectual production. See Madhavi Sunder, IP³, 59 STAN. L.R. (forthcoming 2006). See also Margaret Chon, *Intellectual Property and the Development Divide*, 27 CARDOZO L. REV. 2813 (2006) (arguing in favor of guiding principles to address issues of development, such as food security, education, and health care within the intellectual property regime).

¹⁰³ Alan O. Sykes, *TRIPS, Pharmaceuticals, Developing Countries, and the Doha "Solution,"* 3 CHI. J. INT'L L. 47, 60-61 (2002); see generally Amy E. Carroll, *A Review of Recent Decisions of the United States Court of Appeals for the Federal Circuit: Comment: Not Always the Best Medicine: Biotechnology and the Global Impact of US Patent Law*, 44 AM. U. L. REV. 2433 (1995) (discussing the research and development in biotech industry and examining the pros and cons of U.S. patent law on both international development and domestic biotechnological progress).

¹⁰⁴ TRIPS, *supra* note 59, art. 30.

Under international law, the adverse impact of the HIV/AIDS pandemic imposes obligations *erga omnes* on the international community.¹⁰⁵ In other words, the adverse effects of the HIV/AIDS pandemic are a concern and responsibility of the international community. As U.S. President George Bush argued in his 2003 State of the Union address when announcing a 15 billion dollar United States pledge to address the crisis, the United States and the international community have a moral obligation to do something to address the worst public health pandemic in human history.¹⁰⁶ To paraphrase President Bush, the “miracle” of modern medicine in the developed world made it incumbent for developed countries to do everything within their power to engage in treatment, prevention, and care of those affected by the HIV/AIDS pandemic.¹⁰⁷ In my view, the adverse impacts of the HIV/AIDS pandemic impose not only moral but legal obligations on the entire international community. In other words, the adverse human rights effects of HIV/AIDS are a concern and responsibility of the international community. As a result, the protections of patent rights under the TRIPS Agreement must be balanced against the obligations *erga omnes* that the international community owes to those suffering as a result of the HIV/AIDS pandemic.

Moreover, the TRIPS Agreement does not make any specific reference prohibiting derogation in the event of an emergency.¹⁰⁸ To the contrary, it lists certain situations under which a nation may be relieved of certain obligations.¹⁰⁹ In addition, the recognition of the balancing of patent rights and public health concerns embodied

¹⁰⁵ *Barcelona Traction, Light and Power Co., Ltd. (Belgium v Spain)*, 1970 I.C.J. 3, 32 (Feb. 5). For further elaboration, see Joost Pauwelyn, *A Typology of Treaty Obligations: Are WTO Obligations Bilateral or Collective in Nature*, 14 EUR. J. INT'L L. 907, 916-922 (2003) (discussing the collective nature of obligations such as *erga omnes* obligations).

¹⁰⁶ George W. Bush, President of the United States, State of the Union Address (Jan. 31, 2003), <http://www.whitehouse.gov/news/releases/2003/01/20030128-19.html>. President Bush asked the Congress to commit \$15 billion over the next five years, including nearly \$10 billion in new money, to aid the fight against AIDS in Africa and the Caribbean. *Id.*

¹⁰⁷ *See id.*

¹⁰⁸ *See* TRIPS, *supra* note 59.

¹⁰⁹ *Id.* art. 31.

in the Doha Declaration on TRIPS and Public Health, Article 31 of the TRIPS Agreement, and the proposed Article 31 *bis* confirm that compulsory licensing and reverse engineering are already contemplated under the TRIPS Agreement.¹¹⁰

Beyond this, a question might arise regarding whether States that have not effectively addressed the issue of AIDS through certain known measures in existence today have contributed to the necessity through their acts or omissions. In the case concerning the *Gabcikovo-Nagymaros Project*, the ICJ found that Hungary could not rely on necessity to justify certain derogations from its obligations under a treaty where it had contributed to the peril from which it sought to protect itself.¹¹¹

One can draw several distinctions between the *Gabcikovo-Nagymaros Project* and the current situation in sub-Saharan Africa. First, in *Gabcikovo-Nagymaros*, the State invoking necessity was a party to the contract that created the peril that it sought to avoid by violating the terms of the treaty.¹¹² As a consequence, the ICJ held that the peril which threatened the State interest in that case came as a direct result of the actions of the State. By contrast, when dealing with the HIV/AIDS pandemic, no nation is responsible for inviting or creating the peril.¹¹³ Some sub-Saharan African countries have rightly come under criticism for their slow and relatively ineffective measures to combat the spread of HIV/AIDS. Cultural beliefs, lack of education, and homophobia have been identified as some of the reasons the response to AIDS has been slower in sub-Saharan Africa than in the developed world.¹¹⁴ However, the inadequate government

¹¹⁰ Doha Declaration, *supra* note 97; TRIPS, *supra* note 59, art. 31.

¹¹¹ Case Concerning the *Gabcikovo-Nagymaros Project*, *supra* note 3 (holding that Hungary was not permitted to invoke the claim of necessity for breaking a treaty to construct a system of locks and dams, where Hungary had previously supported the construction and actively sought its completion).

¹¹² *Id.*

¹¹³ *See id.*

¹¹⁴ *See* Peggy B. Sherman & Ellwood F. Oakley, III, *Pandemics and Panaceas: The World Trade Organization's Efforts to Balance Pharmaceutical Patents and Access to AIDS Drugs*, 41 AM. BUS. L.J. 353, 403 (2004); Sofia Gruskin, *The Impact of Reproductive Subordination on Women's Health: Negotiating the Relationship of HIV/AIDS to Reproductive Health and Reproductive Right*, 44 AM. U.L. REV. 1191, 1197 (1995); Ida Susser, & Zena Stein, *Culture, Sexuality, and Women's Agency in the Prevention of HIV/AIDS in Southern Africa*, 90 AM. J. PUB. HEALTH 1042, 1042-44

responses to the AIDS pandemic should not be overstated. As noted earlier, the huge numbers of infected people, the incredible speed at which the pandemic has spread—the fastest pandemic in human history—as well as reductions in public health spending under the aegis of economic restructuring required by the economic programs of the Bretton Woods institutions, give the pandemic a magnitude well beyond the capacity of a majority of the poor economies of sub-Saharan Africa.¹¹⁵ In addition, sub-Saharan African countries have been shown to be more susceptible to the rapid spread of the disease than others, due to both the nature of the virus strain in most of sub-Saharan Africa and to socio-economic factors (such as poverty) that have contributed to the accelerated spread of the pandemic.¹¹⁶ Poor countries have fewer resources at their disposal to deal with this crisis than do wealthier countries. The fact that a nation is less able to deal with a crisis than another should not lead to the conclusion that they have therefore contributed to the crisis.

Second, in the *Gabcikovo-Nagymaros* case, Hungary—though wavering on the pace of the project—stood by the construction of the project for twelve years before abandoning it on the grounds of necessity.¹¹⁷ The widespread transmission of AIDS was never a favored policy of any government in Sub-Saharan Africa and has been a concern for all governments since its inception in the early 1980s. The declaration of necessity on the part of developing

(2000); see also PhRMA, *Challenges: Social and Political Issues*, <http://world.phrma.org/challenges.html> (for a general description of the problems of HIV health care in the developing world).

¹¹⁵ See James Thuo Gathii, *Balancing Patent Rights and Affordability of Prescription Drugs in Addressing Bio-terrorism: An Analysis of In Re Ciprofloxacin Hydrochloride Antitrust Litigation*, 13 ALB. L.J. SCI. & TECH. 651, 660 (2003); see also UNAIDS, *Fact Sheet: Sub-Saharan Africa* (2003), http://data.unaids.org/Publications/Fact-Sheets04/FS_SubSaharanAfrica_Nov05_en.pdf.

¹¹⁶ See UNAIDS, *AIDS Epidemic Update*, 16-18, (Dec. 2002), http://data.unaids.org/Publications/IRC-pub03/epiupdate2002_en.pdf; see also James Orbinski & Bernard Pecoul, *G8: Drugs for Neglected Diseases*, June 24, 2002, http://www.msf.org/msf/international/invoke.cfm?objectid=05C7C503-7F90-4BDF-81FE0AD399CFCF44&component=toolkit.article&method=full_html (arguing that G8 nations need to do more to make inexpensive drugs available to poverty stricken countries because of susceptibility to disease, as well as stating the fact that HIV/AIDS kills eight million people a year, mostly in sub-Saharan Africa).

¹¹⁷ Case Concerning the *Gabcikovo-Nagymaros* Project, *supra* note 3, at 45-56.

nations does not indicate that they have contributed to the peril by not acting earlier. To the contrary, the declaration of necessity is a last ditch effort to stem the tide of AIDS, taken after previous measures proved ineffective.

Finally, since compulsory licensing or reverse engineering would be temporary solutions to lack of treatment, it does not necessarily follow that such conduct would seriously impair the patent protections of the TRIPS Agreement. This is particularly so because access to affordable drugs would release resources for care and prevention efforts. As soon as the circumstances of grave peril disappear, the necessity requiring compulsory licensing would reduce dramatically over time. At that point, sub-Saharan African countries could re-establish conformity with their obligations under the TRIPS Agreement. The TRIPS Agreement already recognizes that the least developed countries do not have to come into full compliance until 2016. A majority of the least developed countries are in sub-Saharan Africa and are among some of the hardest hit by the HIV/AIDS pandemic. It is therefore credible to argue that compulsory licensing for a limited time to address a grave and imminent peril in these countries is already acknowledged by the compliance timetable of the TRIPS Agreement.

The "grave and imminent peril" requirement of invoking the plea of necessity is met by the quickly spreading nature of the pandemic, particularly in countries where prevalence rates are still low. Paragraph 1 of the Doha Declaration on TRIPS and Public Health recognizes the public health crisis associated with the HIV/AIDS pandemic, malaria and tuberculosis.¹¹⁸ Despite medical advances towards the treatment and prevention of AIDS, the illness could kill an estimated 68 million people worldwide if current measures are not drastically expanded.¹¹⁹ The fact that a danger exists in the long run does not make it any less imminent at the time it is realized. To avoid the long-term peril, emergency measures need to be taken now.¹²⁰ Furthermore, the worst of the

¹¹⁸ Doha Declaration, *supra* note 97, ¶ 1.

¹¹⁹ Arlene Getz, *The Epidemic is Growing in Frightening Ways*, NEWSWEEK, July 5, 2002, http://www.24hourscholar.com/p/articles/mi_kmnew/is_200207/ai_kepm312971.html.

¹²⁰ See UNFPA.org, *Women and HIV/AIDS: Confronting the Crisis*, http://www.unfpa.org/hiv/women/docs/women_aids.pdf.

pandemic is yet to come as the following quote illustrates:

The extent of the epidemic is only now becoming clear in many African countries, as increasing numbers of people with HIV are now becoming ill. In the absence of massively expanded prevention, treatment and care efforts, the AIDS death toll on the continent is expected to continue rising before peaking around the end of the decade. This means that the worst of the epidemic's impact on these societies will be felt in the course of the next ten years and beyond. Its social and economic consequences are already being felt widely not only in health but in education, industry, agriculture, transport, human resources and the economy in general.¹²¹

For example, while infection rates in West Africa remain lower relative to those in Southern Africa, the prevalence rate is rising quickly.¹²² The HIV prevalence rate in Nigeria has grown from 1.9% in 1993 to 5.4% in 2003, with some Nigerian States experiencing prevalence rates as high as 6.9%.¹²³

As I have suggested, one of the ways to safeguard the health of the people threatened by AIDS is to make treatments and drugs available that the majority of the population cannot currently afford. In order to make such treatments accessible to the indigent in developing nations, certain additional measures—including care and support—must be taken by their governments.¹²⁴ Treatment would be achieved in part through compulsory licensing and parallel imports of drugs.¹²⁵

III. Conclusions

In this paper, I have argued for justified disobedience of the

¹²¹ Fredriksson & Kanabus, *supra* note 70.

¹²² *Id.* West Africa is relatively less affected by HIV infection, but the prevalence rates in some countries are creeping up. In west and central Africa HIV prevalence is estimated to exceed 5% in several countries including Cameroon (6.9%), Central African Republic (13.5%), Côte d'Ivoire (7.0%) and Nigeria (5.4%). *Id.*

¹²³ *Id.*

¹²⁴ See Annabel Kanabus, Jenni Fredriksson & Rob Noble, *HIV/AIDS Treatment and Care in Resource Poor Communities*, AVERT ORG., July 26, 2005, <http://www.avert.org/hivcare.htm>.

¹²⁵ Peter Piot, Executive Director, UNAIDS, Remarks at the 11th Conference on HIV/AIDS and STDs in Africa (Sept. 1999) (transcript available from Fondation du Présent, <http://www.fdp.org>).

strong protections that patents receive under the TRIPS Agreement in order to facilitate access to essential drugs in developing countries. I have shown that the defense of necessity under the doctrine of State responsibility can be invoked to preclude liability on the part of sub-Saharan African countries that engage in compulsory licensing and reverse engineering. The adverse impact of the HIV/AIDS pandemic on the continent meets both the conditions of an essential State interest as well as that of a grave and imminent peril.

I must make it clear that I am not suggesting that owners of patents should not be compensated when countries decide to infringe patents to facilitate access to essential medicines. Although sub-Saharan African countries that most need these drugs may not be able to afford compulsory licensing, there are a number of funding mechanisms that could fill this gap. At this point, various compensation issues arise, including the mechanism for setting compensation rates. Resolving these procedural issues should not stand in the way of expeditiously and ambitiously expanding access to essential drugs to address one of the greatest public health challenges of all time.

By ensuring predictable access to affordable drugs, compulsory licensing and reverse engineering would help transform the HIV/AIDS pandemic from a virtual death sentence into a treatable disease. Hence, those infected with the virus could live longer and more dignified lives. These advances would provide new hope, especially in countries in sub-Saharan African countries where infection rates have reached as high as 30% of the population.¹²⁶ Such progress would also lessen the disparity of unequal access between the rich and the poor.¹²⁷

Finally, I am not the first to call for justified disobedience of

¹²⁶ See U. Pa. Afr. Studies Center, *Africa: AIDS, New World Health Plan*, <http://www.africa.upenn.edu/afrfocus/afrfocus.html>. Southern Africa is home to about 30% of people living with HIV/AIDS worldwide, yet this region has less than 2% of the world's population. *Id.*

¹²⁷ See Piot, *supra* note 125 (noting the gap between rich and poor countries in caring for people with HIV is becoming morally reprehensible and that the gap in care must be bridged from several different directions including the efforts and progress made by the UN and a number of countries in negotiation with the pharmaceutical industry to make drugs more accessible). See also Uche Ewelukwa, *Patent Wars in the Valley of the Shadow of Death: The Pharmaceutical Industry, Ethics, and Global Trade*, 59 U. MIAMI L. REV. 203 (2005).

some trade regime rules. The late Professor Robert Hudec strongly argued in favor of United States noncompliance with its obligation to resolve disputes regarding whether countries had violated its WTO rights under the Dispute Settlement Body (DSB).¹²⁸ In his view, the United States could engage in unilateral sanctions against countries found to be in violation of its trading rights, particularly its international intellectual property rights, as long as the WTO would still be able to meet its trade liberalization mandate sooner rather than later.¹²⁹ For Professor Hudec, greater liberalization of the trading regime was a benefit worth the United States violating its obligations under the WTO's Dispute Settlement Understanding.¹³⁰

Here, I have argued that a strong case can be made on the defense available under international law that will preclude countries engaging in compulsory licensing from being in violation of their obligations to protect patents under the TRIPS Agreement. Unless we proceed from the premise that even a *de minimis* departure from the patent protections required under the TRIPS Agreement constitutes a TRIPS violation, there is no reason why a defense of necessity would not be available in principle.¹³¹

To close on a hopeful note, it seems the DSB would be open to an argument analogous to the one I have developed here. In *Canada – Term of Patent Protection*, the Appellate Body of the WTO's highest dispute settlement tribunal held that it did not prejudge the interpretation of Articles 7 and 8 of the TRIPS Agreement, which contemplate balancing between the rights of patent holders and those of consumers of patent products.¹³²

¹²⁸ Robert Hudec, *Thinking About the New Section 301: Beyond Good and Evil*, in AGGRESSIVE MULTILATERALISM, 113-59 (Jagdish Bhagwati & Patrick Hugh eds., 1990).

¹²⁹ *Id.*

¹³⁰ *Id.*

¹³¹ Notably Justice Scalia has rejected analogous arguments in the context of sovereign debt where New York creditors argued that a default on a sovereign debt contract performable in New York would undermine the status of New York as the financial capital of the world. Justice Scalia argued that such an argument was speculative and remote and did not rise to an effect within the U.S. See *Republic of Arg. v. Weltover, Inc.*, 504 U.S. 607, 618 (1992).

¹³² WTO Appellate Body Report, *Canada – Term of Patent Protection*, ¶ 101, AB-2000-7, WT/DS170/AB/R (September 18, 2000).

Rather, the Appellate Body found these Articles would await future interpretation. That day will be coming soon. And when it does, the plea of necessity could provide an additional legal basis to promote a balance of the rights of patent holders of antiretroviral drugs and the interests of millions of potential consumers who cannot afford them and yet desperately need them.